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Reliability Assessment Techniques for Medical Procedures

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Abstract

Healthcare aims to deliver good patient outcomes. However deviations in the application of medical procedures can result in failure to deliver reliable care, variation in patient results, waste of hospital resources and increase of risk to staff and patients. Venepuncture – the act of taking blood samples for laboratory tests – has been practised for centuries and is still one of the most common invasive procedures in healthcare. Each step of the procedure can affect the quality of the sample and is thus important for preventing rejection of blood specimens, patient and staff injury and even death. There is evidence that, despite published guidelines, there is wide variability in terms of the procedure, its duration and success rates. This variability can depend on numerous factors: material factors, such as equipment and tubes used during the drawing of blood, and staff factors, such as tourniquet technique and skill of the individual. If the variability effects on outcomes can be evaluated in terms of process reliability and efficiency, potential changes to the current medical practice can be tested before they are proposed and implemented. In this paper a reliability assessment technique based on engineering reliability modelling methods is proposed. A technique based on Petri nets and simulation is presented which can be used to mimic and analyse the performance of a medical procedure through graphical and probabilistic modelling features. The technique can be used to demonstrate variations in the venepuncture procedure affect the outcomes, such as reliability and the duration of the procedure. Different scenarios of resource allocation can be analysed and the most critical steps of the procedure identified. The proposed technique is illustrated using the information gained from interview and questionnaire responses from doctors and phlebotomists working in UK hospitals.

1. Introduction

Health and wellbeing is one of the main global societal concerns, which is important in delivering high levels of employment, productivity and social cohesion in economy. Due to increasing and aging population safe, efficient and sustainable healthcare is the goal, whose attainment contributes to addressing these concerns. For example, according to World Health Organisation (WHO) guidelines for safe surgery [1], there is worldwide evidence of substantial public health harm due to inadequate patient safety. These guidelines are set to reach the goal of error-free procedures and to reduce adverse consequences of unsafe healthcare. Designing tools for safety assessment and identifying solutions for patient safety could save lots of lives. For instance, analysing standards of medical procedures in terms of scenarios with errors, such as surgical errors, lack of communication, equipment failures or inadequate resources, could help to enhance best-practice guidelines and mitigate consequences of healthcare errors. Such analysis can also be used to look for ways to increase the reliability of medical procedures and minimise the risk of death.

In addition to patient safety, hospitals need to make decisions on how to provide high-quality healthcare and spend the available money efficiently, especially due to an increasing demand to reduce healthcare costs. In order to achieve efficient healthcare, such decisions mainly relate to appropriate capacity and organisation of the hospital. Hospital capacity should be carefully planned and better procedure efficiency achieved by optimal use of resources, which would lead to removal of process bottlenecks and reduction of waiting time. According to Institute to Healthcare Improvement (IHI) applying reliability assessment techniques in healthcare can help to reduce "failures" in care, increase its consistency and improve patient outcomes [2]. In the context of funding cuts and rises in demand allocating resources in healthcare is a very difficult problem [3]. Overall, developing modelling tools for reliability and safety assessment of medical procedures could have significant impact on patient safety, as well as financial benefits to society due to increased efficiency and productivity of medical teams. Using such models, effects of potential solutions to improve medical procedures could be evaluated before investments are made and solutions are implemented in practice. A model for a medical process can be used to plan investments in capacity where service is also expecting a significant increase in demand and can help to understand the relationships between parts of the system and test different policies and circumstances in a virtual experiment.

This paper demonstrates the analysis of the efficiency and reliability of a medical procedure using modelling techniques that have previously been used to assess the reliability of maintenance procedures. The chosen modelling techniques are Petri nets and simulation, whilst the chosen medical procedure is venepuncture. The venepuncture procedure involves the collection of blood for a vein usually for laboratory testing and was chosen as the initial case study due to it being a frequently performed and relatively simple procedure. Section 2 describes the methodology used to model the procedure, Section 3 describes the venepuncture procedure, Section 4 describes the model, Section 5 presents the results of analysing the procedure with the model and Section 6 gives conclusions and ideas for future work.

2. Methodology

The reliability of the medical procedure is defined here as the proportion of times the procedure results in a successful outcome, whilst efficiency is defined in terms of the amount of resources and time required to complete the procedure. In order to analyse the efficiency and reliability of a medical or maintenance procedure, it is necessary to:

1. Understand its constituent tasks (timings, input resources, processing that occurs within the task, outputs etc.) and the sequencing constraints between those tasks (e.g. which tasks are prerequisites to another).
2. Develop a model for the complete procedure which can generate probabilistically accurate outcomes from which reliability and timing statistics can be generated.

This section outlines the methods used in this paper for each of those steps.

2.1 Data Collection

A three phased approach was applied to collecting data on the tasks and structure of the venepuncture procedure. A literature review was carried out to understand the current knowledge, both theoretical and practical, on the procedure. In order to understand current practice in UK hospitals and fill in gaps in the required data not found in the literature, further data was then gathered from a small sample of doctors and phlebotomists working in two UK hospitals. Interviews, comprising of questions that were pre-prepared as well as those that arose during the discussion, were conducted with two junior doctors and two phlebotomists from a UK hospital, each taking around 30 minutes to complete. Using the knowledge gained from the literature review and interviews, a detailed online questionnaire was then designed, comprising of 40 specific questions. This was then distributed to doctors working at two UK hospitals. A total of 17 responses were received from this questionnaire. Overall, data was collected from 19 doctors (17 of which had less than 2 years post-qualification experience) and 2 experienced phlebotomists. All had received some training in venepuncture with most having received classroom, workbook and supervised practical based training.

2.2 Coloured Petri Nets and Simulation

Timed coloured Petri nets were chosen as the technique for analysing the medical procedure as they are especially well suited to modelling and validating complex processes. Petri nets are widely used in reliability engineering to model hardware failure and maintenance processes. For example, Reed et al [4] used the technique to analyse the reliability and efficiency of maintenance within the service support system of a functional product and Prescott et al [5] used the technique to model track ballast maintenance for a rail network. However, to the authors' knowledge, they have not previously been applied to the modelling of medical procedures.

Petri nets are a graph based tool that can be used to model the dynamics of many types of system, see Schneeweis [6]. Specifically, a Petri net is a directed bipartite graph in which each node represents either a transition or place, shown in diagrams as a rectangle and hollow circle respectively. Directed arcs linking places to transitions are known as input arcs and those connecting transitions to places are known as output arcs. Places may contain 0 or more tokens, represented by filled circles, and it is the distribution of tokens through the net, known as the net marking, that describes the state of the system. A transition is enabled when tokens in the input places can simultaneously meet the conditions specified for the input arcs and transition itself. An enabled transition can fire, removing the enabling tokens from the input places and outputting tokens to the output places according to the conditions specified for the output arcs. For standard Petri nets, the input and output conditions for an arc are limited to the specification of a number of tokens, known as the arc multiplicity. Only one transition can fire at any instant of time, regardless of the number of transitions that are simultaneously enabled. An example of a transition, showing the before and after net markings, is shown in Figure 1.

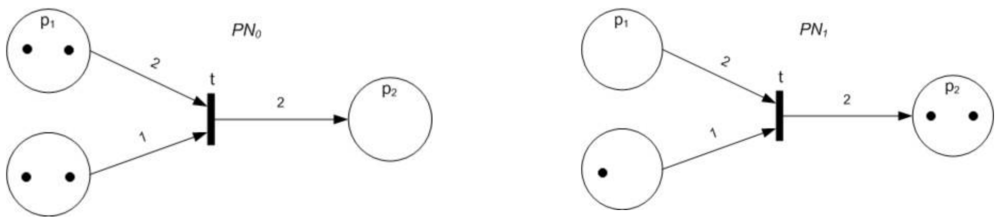

Figure 1. An example Petri net prior to and after firing of the transition.

Timed Coloured Petri nets (TCPN) [7] are an extension to Petri nets that combine the power of Petri nets with that of a high level programming language. In TCPN, a data value, known as a colour, and a timestamp to be attached to tokens. Each place in a TCPN defines the type of data that its tokens can contain (e.g. integer, string or a defined complex type), whilst arcs and transitions may specify complex conditions, in the form of programming language functions, in addition to the standard multiplicity arc conditions. Transitions may also specify functions that modify the data and increment the timestamp of the output tokens when they are fired. Simulation of a TCPN involves the use of a simulation clock and tokens with a timestamp lower than this value are ignored. As is typical in discrete event simulation (DES), the simulation clock increments by the smallest amount necessary to enable at least one transition whenever no transitions are otherwise enabled. Karnon et al [8] discussed the application of DES within a health care setting.

3. The venepuncture procedure

This section describes the venepuncture procedure based on the literature review and data collection exercise.

3.1 Task and procedure structure

According to the WHO guidelines [9] the recommended tasks and task sequence for the procedure is as follows:

1. Assemble the equipment.
2. Preparation: Complete paperwork, identify and prepare the patient.
3. Find vein and select entry site.
4. Apply tourniquet.

5. Perform hand hygiene.
6. Disinfect the entry site.
7. Insert needle and fill the sample tubes.
8. Remove tourniquet - suggests removing the tourniquet as soon as blood flow is established and always before it has been in place for two minutes or more.
9. Post sample: Prepare samples for transportation, clean surfaces and complete patient procedure.

However, the data collected in the interviews and survey showed that many medics performed the procedure differently to these guidelines. The most common deviations found in the data were:

- Performing hand hygiene prior to applying the tourniquet (52% of medics).
- Application of tourniquet prior to finding the vein and selecting the entry site (71% of medics).
- Skipping the disinfection step (14% of medics).
- Release of tourniquet sometime after blood flow is established:
    - During filling of last sample tube before it is full (14% of medics).
    - When all sample tubes are full (72% of medics).

3.2 Resources and Equipment

The resources and equipment involved in the procedure are a patient, a medic, gloves, hand wash, disinfectant, tourniquet, blood-sampling devices (needles and syringes), gauze, tape, laboratory forms, specimen labels, writing equipment and sharps container. The medics involved in the interviews and questionnaire data reported that patients varied in how visible and prominent their veins were and this strongly influenced the difficulty of the finding vein and collecting blood sample tasks. Veins were reported as being much less visible and prominent in patients who are elderly, with certain illnesses such as alcoholism or undergoing certain treatments such as chemotherapy. Three types of needle were found to be commonly used by the medics: hypodermic single-use needle and syringe; vacuum-tube system; and winged steel needle. For the model, it is assumed that all the required equipment is available at the location at which the procedure is performed. The data showed that medics either used a trolley containing all the equipment or collected equipment from the ward in which the patient was situated – phlebotomists always used a trolley whilst almost all doctors collected equipment from the ward. A common complaint was that the layout of the required resources on wards was non-standardised with locations often not labelled or equipment sometimes missing or stored in unexpected places. This was a particular problem for doctors working on an unfamiliar ward or during night-shifts when help was less readily available.

3.3 Failure Modes

The venepuncture procedure has a number of failure modes, the most important in terms of frequency and/or consequence are:

1. Failure to obtain a sample from the patient during single attempt. The data suggested that the probability of failure to obtain a sample from a patient varied considerably between individual patients depending on the prominence of their veins. For those not from a patient group with tendency for non-prominent veins (e.g. elderly), the reported failure probability ranged between approximately 1% and 30% with a modal value of 10%. For patients from a patient group with tendency for non-prominent veins, the data suggested that the failure probability ranged between approximately 15% and 80% with a modal value of 25%. The failure to obtain a sample from a patient results when the medic is unable to obtain a sample from the patient within a reasonable number of attempts. In such cases, the task is usually passed onto another, often more senior or experienced, medic. The number of attempts that is considered reasonable depends on a subjective assessment of the individual case, however 77% of the medics from whom data collected had a defined upper limit which varied from 3 attempts (53% of those with upper limit) to 6 attempts (15% of those with upper limit).
2. Needle stick injury (NSI) to medic. This occurs when a medic accidentally pierces themselves with a used needle and is considered very serious due to the risk of transmission of blood-borne diseases. Gaffney et al [10] found that 72% doctors had acquired a needle stick injury performing venepuncture within a 6 month period, with less than 5% of these being reported. Jagger et al [11] reported that the rate of NSI per piercing attempt at a university hospital varied by needle type as shown in Table 1 (note that the rates are only shown here for the needle types introduced in Section 3.2). The mean estimated probability of a NSI per piercing attempt given by medics in the interviews and questionnaire was approximately 0.1%, with no significant difference between needle types found due to the small sample size. Although this estimate is significantly higher than found by Jagger et al, it is plausible given the low proportion of incidents that are reported as found by Gaffney et al [10].

Needle Type	NSI probability per piercing attempt
Single use needle and syringe	0.0069%
Winged steel needle	0.0182%
Vacuum tube system	0.0254%

Table 1. Rate of needle stick injuries for various needle device types from Jagger et al [11].

3. Rejection of obtained sample from the lab. A study of 453 labs by Jones et al [12] found that in total 0.35% of samples received by a lab were rejected prior to testing, although the rejection rate varied by lab

with the 10th, 50th (median), and 90th percentiles being 1.35%, 0.31%, and 0.06%, respectively. The rejection of a sample by the lab is an example of an unrevealed failure mode within the venepuncture procedure, since the failure will not be apparent to the medic at the time the sample is collected. The most common reasons for rejection are:

a. Haemolysis of a sample where red blood cells have ruptured and released their contents into the surrounding blood plasma. This was found to be the most common reason for lab rejection in the study by Jones et al at 60% of all rejections. A study of 353 blood sampling events [13] found that the duration with which the tourniquet is applied during blood sampling was the most significant factor in causing haemolysis, with times of over one minute associated with an almost 20 times greater probability compared to times of under one minute, whilst no relationship between number of attempts and haemolysis was found. Blazys [14] and Becan-McBride [15] also mentioned that releasing the tourniquet within one minute of application reduced the risk of haemolysis. A review of the causes of haemolysis is given by the ENA Emergency Nursing Resources Development Committee [16].
b. Insufficient sample quantity. Found to be the second most common cause of rejection at 12% of all rejections in the study by Jones et al [12].
c. Contamination of sample.
d. Incorrect labelling.

4. Venepuncture Procedure Model

In this section, a description is given of the model developed for analysing the venepuncture procedure.

4.1 Resource Modelling

A patient is modelled as an entity with a difficult patient group attribute that is assigned the value true if they belong to a patient group associated with difficulty in obtaining a blood sample (e.g. elderly patients) and false otherwise. They are also randomly assigned a value between 0 and 100 from the uniform distribution which indicates their relative vein visibility amongst patients within their difficult patient group category with values of 0, 50 and 100 indicating the 0^{th} percentile (best), median (average) and 100^{th} percentile (worst) visibility.

4.2 Task Modelling

Task Durations: The uniform distribution was chosen to model the duration of each task with minimum and maximum values chosen based on the data gathered from the interviews and questionnaire with extreme outlier values excluded. The uniform distribution was deemed most appropriate since the data suggested that the time to complete a task was approximately equally probable for all values within a certain range. Table 1 gives the estimated minimum and maximum durations for each task. For the task “Assemble

Equipment”, distinct durations are given for the case where the medic has an equipment trolley or is working on a familiar ward and the case where they are working on an unfamiliar ward with non-standardised layout. For the task “Find Vein”, separate duration models are given depending on whether the patient is categorised as having normal or difficult veins as shown in Table 2.

Task Description (see section 3.1)	Minimum and maximum duration in seconds
1 - Preparation	90 - 180
2 – Assemble Equipment	Familiar ward or trolley: 20 - 40, Unfamiliar ward: 40 - 360
3 – Hand Hygiene	20 - 40
4 – Find vein	Normal veins: 15 - 60 Difficult veins: 60 - 240
5 – Apply tourniquet	5 - 10
6 – Disinfect entry site	15 - 30
7 – Pierce and fill sample tubes	20 – 80
8 – Remove tourniquet	5 -10
9 – Post sample	60 -180

Table 2. Durations for key tasks in venepuncture procedure.

Pierce attempt model: The outcome of a pierce attempt is modelled as having two failure modes. The first failure mode is a NSI which is assumed to occur with a probability of 0.1%. If a needle stick injury does not occur, the second failure mode is failure to collect a blood sample for which the probability of occurrence is assumed to vary between individual patients and be influenced by whether the patient belongs to a patient group with tendency for non-prominent veins or not. For patients that do not belong to one of those groups the failure probability is assumed to be distributed according to the triangular distribution with minimum, modal and maximum values of 1%, 10% and 30% respectively. For those that do belong to one of those groups, the distribution minimum, modal and maximum values are assumed to be 15%, 25% and 80%.

Lab rejection model: Based on the reviewed literature, it is assumed that the rejection rate due to the occurrence of the haemolysis failure mode is 0.01% when the duration between piercing application and release of the tourniquet during sample collection is less than 1 minute, 0.05% for less than 1 minute 30 seconds and 0.20% for greater durations. For the purpose of the model, the tourniquet duration is calculated as the time between the completion of the ‘Apply tourniquet’ task and the initiation of the ‘Remove tourniquet’ task. A total rejection rate of 0.14% due to the occurrence of the other failure modes of insufficient sample quantity, contamination and incorrect labelling is assumed and is also assumed to be independent and non-competing with the haemolysis failure mode.

4.3 Procedure Modelling

The CPN Tools software program [17] was used to construct Petri net models of the procedure and simulate its performance. It was decided that three variations of the procedure that were identified from the literature review and data collection would be modelled and analysed:

A. WHO guidelines with tourniquet released when blood flow established for patients not from the difficult patient category and with medics working on familiar ward.
B. Same as variation A but with patients from the difficult patient category and medics working on unfamiliar ward.
C. Same as variation A but with find vein after tourniquet application and tourniquet released after all sample tubes filled.

It is assumed if a medic fails in an attempt to obtain a blood sample (e.g. missed vein), and if less than 3 failed attempts have been made, then they perform the corrective action of removal of the tourniquet before continuing the procedure from the find vein task. If a NSI or three consecutive failures to obtain a sample occur then no further attempts are made. Since the lab rejection failure modes are non-revealed, the procedure continues as normal without any corrective actions when they occur.

5. Results and Analysis

The model was simulated 5000 times for each variation of the procedure. Table 3 shows the statistics for the completion time and tourniquet application time for each procedure variation that were obtained. As shown, the procedure time is on average far greater for variation B, where the procedure is performed for a patient from the difficult patient category on an unfamiliar ward, than for the other variations. This has implications for planning medic resources and the time wasted due to wards with non-standard or poor layouts. It also shows that whilst the mean tourniquet time is further than one standard deviation below the recommended time of one minute for low risk of haemolysis for variations A and B, for variation C the mean time is greater than two minutes. Variation C is commonly performed in practice according to the collected data and, as shown by the model data, results in a tourniquet time with a significant increase in the risk of lab rejection due to haemolysis.

Variation	Procedure Mean	Procedure Standard Deviation	Tourniquet Mean	Tourniquet Standard Deviation
A	448	64	53	7
B	811	188	52	7
C	455	64	140	23

Table 3. Statistics for times in seconds for each procedure variation obtained from simulation model.

Figure 2 shows a histogram of the simulated tourniquet times for variation A and C of the procedure. Note that variation C almost always results in a tourniquet time below the one minute recommended time limit to minimise risk of haemolysis, whereas this is never the case for variation C.

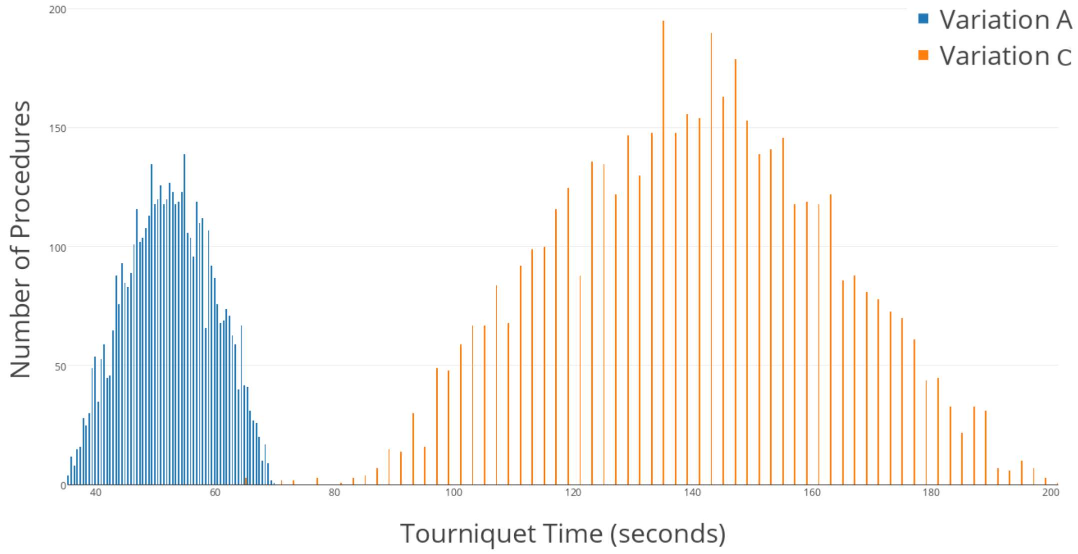

Figure 2. Histogram showing the distribution of the simulated tourniquet application times for variations A and C of the procedure.

Table 4 shows the number of failures that occurred in the simulated procedures for each procedure variation. As expected, variation B, with patients from the difficult patient group, results in a significant number of failures to collect a sample due to the 3 failed attempt limit being reached. It also shows that the risk of NSI is much higher, due to the higher number of needles involved with repeat attempts.

Variation	Failure to Collect Sample	NSI	Haemolysis Lab Rejection	Other Lab Rejection
A	11	4	1	8
B	189	12	1	7
C	9	5	10	6

Table 4. Number of failures for each failure mode that occurred in 5000 simulations of each procedure variation.

6. Conclusions and Future Work

The results show that the methodology, derived from techniques used to model industrial maintenance procedures, has potential for analysing the performance of medical procedures. In the case of the venepuncture procedure that was researched and analysed here, two important findings are that better organisation and standardisation of equipment locations in wards would improve efficiency significantly and that certain variations to the procedure that are common in practice may be resulting in a significant increase in the risk of haemolysis. This failure mode may have high consequences since, as an unrevealed failure mode only discovered at the laboratory, it significantly increases the time until patient blood sample test results can be obtained.

Only a limited sample size of self-reported data was obtained from medics during the data collection phase. Therefore, the level of confidence that can be given to the actual results from the modelling analysis of the venepuncture procedure is limited. Nevertheless, they suggest that the collection of further data, possibly including live observations of medics performing the procedure, would be valuable. Areas in which additional data would be particularly useful would be analysis of vein prominence within various patient groups (e.g. illness, treatment and age), the influence of vein prominence on failure rates and the study of failure rates in each failure mode for different needle types. This data could be used with a further developed model of the procedure to make evidence based recommendations on best practice, such as procedure structure and choice of needle based on the patient attributes.

Venepuncture was chosen as the initial application for the method due to it being a relatively simple and common procedure. However, this simplicity also limited the scope for new insight that could be obtained from the analysis. It would therefore be worthwhile extending the study to more complex procedures such as anaesthesia which is performed by a team of medics.

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